JUL 2 8 2005

510(k) Summary of Safety and Effectiveness

Submitter

Mediana Co.,Ltd.
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Company Contact: Gina Y.J.LEE, Specialist of Regulatory Affairs
Date Summary Prepared: March 2nd, 2005

Device Name

Trade Name:	ARGUS VCM series, Vital Signs Monitor
Common Name:	Vital signs measurement devices
Classification Name:	NIBP measurement system (21CFR870.1130), also contains non-invasive pulse oximetry, SpO2 (21CFR870.2700) and clinical electronic thermometer (21CFR870.2910)
Classification:	Class II

Predicate Devices (Legally Marketed Devices)

The predicate devices for Vital signs monitors, Model ARGUS VCM series are:

- **Welch Allyn Protocol Inc.** Vital Signs Monitors, Model 53000 Series cleared by FDA through 510(k) No. **K031740**, and
- **Welch Allyn Protocol Inc.** Vital signs Monitors, Model Propaq LT 802 Series cleared by FDA through 510(k) No. **K033378**, and
- **Nellcor Puritan Bennett** (division of Tyco Healthcare Inc.) Pulse Oximeter, Model N-550 cleared by FDA through 510(k) No. **K021090**, and
- **Welch Allyn Inc.** Vital Signs Monitors, Welch Allyn Vital Signs Monitor (VSM), cleared by FDA through 510(k) No. **K024005**.

Device Description

The ARGUS VCM vital signs monitor is to monitor non-invasive blood pressure, pulse rate, non-invasive functional oxygen saturation of arterial hemoglobin (SpO2) for adult, pediatric and neonate patients and body temperature for adult and pediatric patients in general hospital and alternate care facilities by medically trained personnel. This monitor is available for sale only upon the order of a physician or licensed health care professional.
The Mediana ARGUS VCM vital signs monitor is a lightweight and compact device (180×278×130 mm and 2.7 kg) powered by AC mains (100-240VAC, 50-60Hz) and also powered by internal battery. The monitor provides patient data and monitoring status on 7-segment and LED displays.

Intended Use

The purpose and function of the Mediana ARGUS VCM vital signs monitor is to monitor non-invasive blood pressure (systolic, diastolic, and mean arterial pressures), functional arterial oxygen saturation, pulse rate for adult, pediatric and neonate patients and temperature for adult and pediatric patients in all hospital areas and hospital-type facilities. It may be used during hospital transport and in mobile, land-based environments, such as ambulances, within the specification of the environmental characteristics.

Note: Hospital use typically covers such areas as general care floors, operating rooms, special procedure areas, intensive and critical care areas, within the hospital plus hospital-type facilities. Hospital-type facilities include physician office based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acutecenters.

Note: Intra-hospital transport includes transport of a patient within the hospital or hospital-type facility.

Summary of Technical Characteristics of the Device Compared to the Predicate Devices (Legally Marketed Devices)

The Mediana vital signs monitors, Model ARGUS VCM Series are substantially equivalent to the Welch Allyn Protocol vital signs monitors, Model 53000 Series and Model Propaq LT 802 Series, Nellcor Puritan Bennett (division of Tyco Healthcare Inc.) Pulse Oximeter Model N-550, and Welch Allyn Inc. Vital Signs Monitor, Welch Allyn Vital signs Monitor (VSM).

- The **Non-Invasive Blood Pressure (NIBP)** measurement specifications and performance are equivalent to the Welch Allyn Protocol vital signs monitors, Model 53000 Series and Model Propaq LT 802 Series. Welch Allyn NIBP module POEM is the same NIBP module used in the Mediana vital signs monitors, Model ARGUS VCM Series.
- The **Pulse rate** specifications and performance derived from either Non-Invasive Blood Pressure (NIBP) or Pulse Oximetry (SpO2) are equivalent to the Welch Allyn Protocol vital signs monitors, Model 53000 Series, and the Nellcor Puritan Bennett Pulse Oximeter Model N-550.
- The **Pulse Oximetry (SpO2)** specifications and performance are equivalent to the Nellcor Puritan Bennett Pulse Oximeter Model N-550. Nellcor Oximetry module MP506 is the same SpO2 module used in the Mediana vital signs monitors, Model ARGUS VCM Series.
- The **Temperature** specifications and performance are equivalent to the Welch Allyn Protocol vital signs monitors, Model 53000 Series and the Vital Signs Monitor (VSM). Welch Allyn thermometry module SureTemp® is the same temperature module used in the Mediana vital signs monitors, Model ARGUS VCM Series.

Summary of Performance Testing

The Mediana vital signs monitors, Model ARGUS VCM Series substantially have been tested in accordance with the system V & V plan (#PA300-09000) and summary (#PA300-09013) included with the submission using production equivalent units prior to release to market.

A risk analysis identifying potential hazards and documenting mitigation of the hazards has been developed and applied as part of Mediana design control procedure. Mediana's quality system confirms to 21CFR820, ISO 9001, ISO13485 and CMDCAS ISO 13485 certified by DNV (Det Norske Veritas) and NSAI (National Standards Authority of Irelands).

Conclusions

As stated above, the Mediana vital signs monitors, Model ARGUS VCM Series are safe and effective and comply with the appropriate medical device standards and are substantially equivalent to the earlier identified predicate devices.

- End of Section -

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 8 2005

Mediana Co., LTD.
c/o Mr.Charlie Mack
International Regulatory Consultants
231-6 Nonhyun-Dong
Kangnam-Ku, Seoul,
Kerea 135-110

Re: K051375
Trade Name: Argus VCM series, vital signs monitors
Regulation Number: 21 CFR 870.1130, 21 CFR 870.2700, 21 CFR 880.2910
Regulation Name: System, Measurement, Blood Pressure, Non-Invasive
Regulatory Class: Class II (two)
Product Code: DXN
Dated: May 24, 2005
Received: May 26, 2005

Dear Mr. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051375

Device Name: Argus VCM Series, Vital Signs Monitor

Indications For Use: The purpose and function of the Mediana ARGUS VCM vital signs monitor is to monitor non-invasive blood pressure (systolic, diastolic, and mean arterial pressures), functional arterial oxygen saturation, pulse rate for adult, pediatric and neonate patients and temperature for adult and pediatric patients in all hospital areas and hospital-type facilities. It may be used during hospital transport and in mobile, land-based environments, such as ambulances, within the specification of the environmental characteristics.

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Note: Intra-hospital transport includes transport of a patient within the hospital or hospital-type facility.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051375